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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,817	11/20/2003	Xi Chu		9715

7590 03/17/2006
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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,817	CHU, XI	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2005 and 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-28,35 and 41-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-34,36-40 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed August 31, 2005 and the response to the notice of non-compliant amendment filed December 12, 2005 have been entered. The changes to the drawings and specification have been approved. New claim 50 has been added, and claims 1-28 and 41-49 remain withdrawn from consideration for being directed to a non-elected invention. Amended claim 35 has also been withdrawn for the reasons set forth in the claim objections below. Claims 1-50 are currently pending, of which claims 29-34, 36-40 and 50 are being considered for further examination on the merits.

Claim Objections

2. Claim 35 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

3. Claims 29, 37-40 and 50 are objected to because of the following informalities:

- a) Claim 29, line 5, --of-- should be inserted after "pairs".
- b) Claim 29, line 7, "hinge" should be changed to --hinges--.
- c) Claim 29, line 7, "openning" should be changed to --opening--.
- d) Claim 37 is awkward; the examiner suggests changing "a heart valve of an aortic, mitral, pulmonary, and tricuspid" to --an aortic heart valve, a mitral heart valve, a pulmonary heart valve, a tricuspid heart valve--, and changing all semicolons in the claim to commas.

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- e) Claim 38, line 1, "valves" should be changed to --valve--.
- f) Claim 38, line 2, "opening" should be changed to --opening--.
- g) Claim 39, line 1, "valves" should be changed to --valve--.
- h) Claim 40, line 1, "valves" should be changed to --valve--.
- i) Claim 50, line 2, "form" should be changed to --from--.
- j) Claim 50, line 3, "finer" should be changed to --fibers--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 36 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 34 has the listing of materials include "nanostructure engineered carbon". This is broader in scope than what was originally disclosed in the specification, which disclosed "nanostructure engineered pyrolytic carbon". Because the claimed limitation is broader, it is considered new matter. The examiner suggests inserting --pyrolytic-- after "engineered" to overcome the rejection. Claim 36, which is dependent on claim 34, is rejected for the same reason. On line 2, --pyrolytic-- should be inserted after

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“engineered”. On line 3, the deletion of “pyrolytic” to describe the graphite-carbon domains broadens the claim beyond what is disclosed in the specification. The examiner suggests inserting --pyrolytic-- before “graphite-carbon”. Claim 50 has the listing of materials include “organic binder”. This limitation is also broader than what was originally disclosed in the specification, which discloses “organic thermosetting binders”. See page 3, line 19 and page 16, line 23. Because the claimed limitation is broader, it is considered new matter. The examiner suggests inserting --thermosetting-- after “organic” to overcome the rejection.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 39 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 39 is indefinite because it is unclear what the elements listed as “flat spherical depression, or spherical protrusion” are due to lack of punctuation. How can the depression be flat and spherical at the same time?

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 29-34, 36-40 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Carpentier et al. (USPN 6,039,759, as cited in last office action).

Carpentier et al. discloses a trileaflet prosthetic valve with all the elements of claim 29. See Figs. 21-23 and column 13, lines 7-58 for a trileaflet prosthetic valve (510) comprising an annular valve body (512) having an inner surface and being disposed around a central axis. Three substantially identical leaflets (526, 527, 528) are mounted in the annular valve body (512) and are configured to translate between a closed position impeding blood flow through the valve and an open position allowing blood flow therethrough. The annular body (512) has three pairs of symmetrically placed hinges (522, 524) spaced around on one side (the inside) of the annular body (512) for pivotally supporting the leaflets (526, 527, 528). Each hinge (522, 524), due its shape, has a plane of symmetry containing the central axis and an opening in the form of a recess. Each of the leaflets have opposed ears (530, 532) for engaging the hinges (522, 524) and a flat edge adjacent each of the ears for engaging a surface segment.

Claims 30 and 33, see Figs. 21 and 23 for each of the leaflets (526, 527, 528) further comprising a central surface having a curved outer edge (538) for engaging the inner surface of said annular body (512), an obliquely angled inner edge (536) for engaging adjacent leaflets, and two flat segments adjacent to each ear (530, 532) to guide the motion of the leaflet.

Claim 31, see Figs. 12-14. The shape of the hinge (522, 524) includes surfaces that provide as stop means for arresting movement of the leaflets.

Claim 32, see Fig. 21 for at least three supports (514') for guiding the leaflets (526, 527, 528), each of the supports comprising two flat planes (514'') on the inner surface of the support.

Claim 34, see column 6, lines 64-65 for the valve body being formed from pyrolytic carbon and the leaflet substrates being formed from metal (titanium).

Claim 36 does not necessarily further limit the invention. The claim is dependent on claim 34, which has a listing of materials from which the valve body and the leaflets can be made. In an embodiment wherein the valve body is made from pyrolytic carbon and the leaflets are made from metal, such as in the invention disclosed by Carpentier et al., further limiting the nanostructure engineered carbon material does nothing to limit the embodiment at issue. The examiner suggests amending claim 36 to first limit the material to a nanostructure engineered (pyrolytic) carbon, and then further limit the nanostructure engineered (pyrolytic) carbon as set forth in the claim.

Claim 37 recites only an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Because the trileaflet prosthetic valve of Carpentier et al. is a prosthetic heart valve, it is capable of being implanted into a system of heart valves.

Claim 38, see Figs. 12-14 for the internal opening shape of the hinges being butterfly, or column 13, line 21 for the opening of the hinges (522, 524) being wing-shaped (triangular).

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Claim 39, see Figs. 12-14 for the bottom of the hinges being a spherical depression, as best understood by the examiner.

Claim 40, see column 13, line 21; because the hinges (522, 524) are wing-shaped, the bottoms of the hinges will be half-open.

Claim 50 does not necessarily further limit the invention. The claim is dependent on claim 34, which has a listing of materials from which the valve body and the leaflets can be made. In an embodiment wherein the valve body is made from pyrolytic carbon and the leaflets are made from metal, such as in the invention disclosed by Carpentier et al., further limiting the carbon composite material does nothing to limit the embodiment at issue. The examiner suggests amending claim 50 to first limit the material to a carbon composite, and then further limit the carbon composite as set forth in the claim.

Response to Arguments

9. Applicant's arguments filed August 31, 2005 have been fully considered but they are not persuasive. Applicant argues that the hinges of the instant application are open structures with internal openings, as opposed to the hinges disclosed in the Carpentier patent, which are solid and have no openings in the structure. The examiner disagrees. Looking at the language of independent claim 26, it is required that each of the hinges has an opening. According to Merriam-Webster online dictionary, a definition for "opening" is "2: *something that is open: as a (1): BREACH, APERTURE (2): *an open width: SPAN*". By definition, therefore, it is not required that the openings of the hinges extend through both the inner and outer surfaces of the valve*

body, as shown in Figure 5b of the application. The structure of the recesses defining the hinges (522, 524) of Carpentier meets the definition of “opening”.

10. Applicant also argues that the hinges of Carpentier are disposed on the inner surface of the annular valve body, while the hinges of the instant application, to the contrary, are spaced around on one side of the annular body. In response, the language of claim 26 does not further limit what the side is. Therefore, a “side” can be broadly interpreted as any of a right side, left side, lateral side, top side, bottom side, inside or outside. Accordingly, the hinges of Carpentier disposed on the inner surface of the valve body are indeed disposed on one side of the valve body, the inside.

11. In response to applicant's argument that the leaflets of Carpentier have protrusions (542) that would cause incomplete washing, and potentially result in clotting, applicant is reminded that claim 29 uses the word “comprising”, which makes the claim open. Because the invention can include structural elements in addition to the elements claimed, the inclusion of the protrusions is not precluded. Additionally, Carpentier discloses the structure of the ears as required by claim 29.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

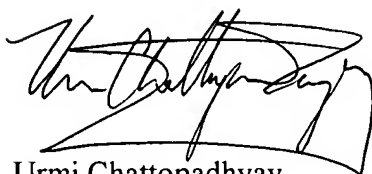
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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner